

ACETAMINOPHEN- acetaminophen tablet
LEADER/ Cardinal Health 110, Inc

8HR Muscle Aches & pain Relief
Acetaminophen Extended-Release Tablets USP, 650mg
Pain reliever/Fever Reducer

Active ingredient (in each caplet)

Acetaminophen USP, 650mg

Purpose

Pain reliever/fever reducer

Uses

- temporarily relieves minor aches and pains due to:
- muscular aches
- backache
- minor pain of arthritis
- toothache
- premenstrual and menstrual cramps
- headache
- the common cold
- temporarily reduces fever

Liver warning

This product contains acetaminophen. Severe liver damage may occur if you take

- More than 6 caplets in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

Allergy alert

acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

Do not use

- with any other drug containing acetaminophen (prescription or nonprescription). If

you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

- if you are allergic to acetaminophen or any of the inactive ingredients in this product

Ask a doctor before use if you have

liver disease

Ask a doctor or pharmacist before use if you are

taking the blood thinning drug warfarin

Stop use and ask a doctor if

- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- new symptoms occur
- redness or swelling is present.

These could be signs of a serious condition.

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

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Overdose warning:

In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222) Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

- **do not take more than directed (see overdose warning)**

adults and children 12 years of age and over

- take 2 caplets every 8 hours with water
- swallow whole; do not crush, chew, split or dissolve
- do not take more than 6 caplets in 24 hours
- do not use for more than 10 days unless directed by a doctor

children under 12 years

- do not use

Other information

- store between 20-25°C (68-77°F)
- **do not use if foil inner seal is broken or missing**

Inactive Ingredients

hydroxy ethyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, sodium starch glycolate, stearic acid.

Questions or comments?

Contact **1-877-770-3183** Mon-Fri 8:00 AM EST to 5:00 PM PST.

Principal Display Panel



ACETAMINOPHEN

acetaminophen tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0626
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg

Inactive Ingredients				
Ingredient Name			Strength	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)				
POVIDONE K30 (UNII: U725QWY32X)				
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)				
MAGNESIUM STEARATE (UNII: 70097M6I3O)				
STARCH, CORN (UNII: O8232NY3SJ)				
HYDROXYETHYL CELLULOSE (140 CPS AT 5%) (UNII: 8136Y38GY5)				
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)				
Product Characteristics				
Color	white (WHITE TO OFF WHITE COLORED)		Score	no score
Shape	OVAL (CAPSULE SHAPED, BICONVEX INTACT FILM COATED TABLETS)		Size	19mm
Flavor			Imprint Code	G;650
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0626-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	03/02/2023	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA		ANDA211544	03/02/2023	

Labeler - LEADER/ Cardinal Health 110, Inc (063997360)

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LEADER/ Cardinal Health 110, Inc